

Sèrial No.: 09/182,102
Filed: October 27, 1999

B2 Sub D1
19. (Amended) A method of identifying the Rad51 genotype of an individual comprising determining all or part of the sequence of at least one Rad51 gene of said individual and comparing said sequence to a known Rad51 gene.

B3 Sub D2
21. (Amended) A method according to claim 20 wherein a difference in the sequence between the Rad51 gene of said individual and said known Rad51 gene is indicative of a disease state or a propensity for a disease state, and wherein said difference in the sequence of the Rad51 gene in the individual results in aberrant Rad51.

Remarks

Claims 18, 19 and 21 are pending. An appendix of the claims is attached for the Examiner's convenience.

Drawings will be submitted at the time the application is allowed.

Applicants are in the process of verifying the reference on page 58, and will address this issue in a forthcoming communication.

Claim 20 has been canceled without prejudice and merged into Claims 18 and 19.

Claim 21 has been amended. Support for the amendment is found at least on page 16, lines 10 and 11.

The Rejections Under 35 U.S.C. Section 112, First Paragraph

Claim 21 is rejected under 35 U.S.C. Section 112, first paragraph, as "not described in the specification in such a way as to enable one skilled in the art.....to make and/or use the invention." More particularly, the Office Action states that in "order to practice the claimed invention one of skill in the art must identify a Rad51 mutation that is associated with the disease" which would require "undue experimentation". Applicants respectfully traverse.

As indicated in the Office Action, In re Wands, 8 USPQ2d 1400 at 1406 (CAFC 1988) lists factors to consider when determining if claimed subject matter meets the requirements of § 112, first paragraph rejection. The factors are: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state

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of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." In re Wands, at 1404. A review of these factors in consideration of the claimed invention shows that the claims are enabled.

Guidance to practice the claimed invention is provided throughout the application. More particularly, page 16, lines 7-16 describe variant Rad51 genes as having a number of mutations which could result in aberrant Rad51 function or levels. Changes in biological function of Rad51 include, for example, altered nucleic acid binding, filament formation, DNA pairing (i.e. D-loop formation), strand-exchange, strand annealing or recombinagenicity (page 9, lines 14-28, page 17, lines 1-17). Each of these characteristics can be identified provided with the present application (see citations provided at page 17, line 9).

Provided with the guidance and examples of the specification, and given that the skill in the art is high, the skilled artisan could reasonably expect to successfully practice the claimed invention. Applicants, therefore, submit that Claim 21 is enabled in accordance with In re Wands, and request that the rejection be withdrawn.

The Rejections Under 35 U.S.C. Section 112, Second Paragraph

Claims 18-21 are rejected under 35 U.S.C. Section 112, second paragraph, as "indefinite." Applicants believe the claims as filed are clear and finite. However, in an effort to expedite prosecution, Applicants have amended the claims in accordance with the Examiner's suggestions. Applicants, therefore, request that the rejection be withdrawn.

The Rejections Under 35 U.S.C. Section 102

Claims 18-20 are rejected under 35 U.S.C. Section 102(b) as anticipated by Ogawa, et al., *Biochimie*, 79:587-592 (1997) (Ogawa). Applicants respectfully traverse.

The present application is a divisional of 09/007,020 filed January 14, 1998 which is a continuation of 60/045,668 filed May 6, 1997 and 60/035,834 filed January 30, 1997.

Ogawa has a stamp on it that recites it was "received" March 5, 1998. Applicants therefore submit that Ogawa is not applicable as prior art against the present invention.


Moreover, Ogawa does not anticipate the present invention. Ogawa compares sequences of Rad51 from different species. Ogawa does not disclose a method for

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identifying cells or Rad51 genotypes of individuals. To anticipate, each and every element must be disclosed. Ogawa does not disclose each element of the claimed invention, therefore, Applicants request that the rejection be withdrawn.

Applicants submit that all the claims are in condition for allowance and an early notification of such is solicited.

Respectfully submitted,
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APPENDIX:

18. (Amended) A method [for] of determining whether a cell contains [identifying a cell containing] a mutant Rad51 gene comprising determining the sequence of all or part of [at least one of the endogenous Rad51 genes] an endogenous Rad51 gene of a cell and comparing said sequence to a known Rad51 gene.

19. (Amended) A method of identifying the Rad51 genotype of an individual comprising determining all or part of the sequence of at least one Rad51 gene of said individual and comparing said sequence to a known Rad51 gene.

21. (Amended) A method according to claim 20 wherein a difference in the sequence between the Rad51 gene of said individual and said known Rad51 gene is indicative of a disease state or a propensity for a disease state, and wherein said difference in the sequence of the Rad51 gene in the individual results in aberrant Rad51.